MASS. H530.300: M38/990

UMASS/AMHERST

312066 0282 3946 0

MASSACHUSETTS

CLINICAL TRIALS

DIRECTORY

FOR AIDS AND HIV-RELATED DRUGS

COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF PUBLIC HEALTH
AIDS OFFICE

JULY 1990

The Department of Public Health would like to thank the members of the Governor's Task Force on AIDS and its Sub-Committee on Clinical Trials and Research who, in 1988 and 1989, gave generously of their time and energy in the development of this directory.

Governor's Task Force on AIDS

Vera Maddox Ajanaku
Hortensia Amaro, Ph.D.
Alexandra Beckett, M.D.
Mona Bennett, M.D.
Paul Black, M.D.
Richard Brown, M.D.
Sen. Edward Burke
Van Dunn, M.D.
Nicholas Dupont
Zoila Torres Feldman, M.P.H.
Robert Galea
George Grady, M.D.
Jerome Groopman, M.D.
Stetson R. Hall, M.P.H.
Martin Hirsch, M.D.
Georgette Jeanty, M.D.
Philip Johnston
Larry Kessler
George A. Lamb, M.D.
Andre T. Lemay
John Mazzullo, M.D.
Rep. John McDonough
Peter L. Page, M.D.
Luis Prado, M.S.
Deborah Prothrow-Stith, M.D.
David Sack
Barbara Stanley, M.S., R.N.
Richard Stevens, Jr.
John Sullivan, M.D.

Sub-Committee on Clinical Trials and Research

Howard Liebman, M.D., chairman

Charla Andrews, M.S.
Norman Beach
Paul Black, M.D.
Neil Blacklow, M.D.
Mark Burridge
Steven D. Busby
Ellen Cooper, M.D.
Duane Draper
John B. Dixon
Zoila Torres Feldman, M.P.H.
Donna Gallagher, R.N., M.S., A.N.P.
Ellen Godfrey, M.P.H.
George Grady, M.D.
Jerome Groopman, M.D.
Martin Hirsch, M.D.
Nancy Karthas, R.N.
Millie Kilmartin
Harvey J. Makadon, M.D.
Ken Mayer, M.D.
Lynne Mofenson, M.D.
Jack Moye, M.D.
Donald O'Dell
Nicole Prudent, M.D.
Nancy Ridley, M.S.
Lawrence Robinson
George Seage, Ph.D.

The Commonwealth of Massachusetts
Executive Office of Human Services
Department of Public Health
150 Tremont Street
Boston 02111

Michael S. Dukakis
Governor

Philip W. Johnston
Secretary

David H. Mulligan
Commissioner

August 1990

Dear Subscriber:

The Massachusetts Department of Public Health AIDS Office is pleased to send you the revised edition of our Clinical Trials Directory. This replaces the original Directory, which appeared in May 1989, and the subsequent appendix published in November 1989.

The Clinical Trials Directory was conceived and developed by the Subcommittee on Clinical Trials and Research established by the Governor's Task Force on AIDS in August, 1988. In this Directory, we have tried to present a complete list of HIV-related clinical trials now open for enrollment in Massachusetts. Each protocol lists, among other things, the goals of the trial, criteria for inclusion in, and exclusion from, the trial, and the telephone number of the researchers and trial administrators who can answer questions and discuss appropriate referral. The information on current HIV/AIDS drug protocols was gathered from researchers throughout Massachusetts. Also listed in this edition are treatment INDs and open label protocols with nationwide accrual.

We would like to take this opportunity to thank the individuals who have contributed to the Directory and ask for any comments or suggestions for improving it.

Please also note that three educational brochures are available to help patients reach an informed decision on whether to participate in a clinical trial. These publications are available in English, Spanish, and, in some cases, Portuguese and Haitian Creole. You may use the order form at the end of the Directory or call 1-800-443-AIDS to order these materials.

We hope that the Directory will be a useful tool for both health care providers and the HIV-infected community in the fight against AIDS.

Sincerely,

David H. Mulligan
Commissioner

TABLE OF CONTENTS

Finding Information in this Directory iii

Sample Listing v

Cross References
- Diagnosis/Protocol vi
- Drug/Protocol viii
- Drug Type/Protocol x
- Location/Protocol xi
- Treatment INDs and Open Label Protocols xiv

Protocol Information
- 01, Project P53 1
- ACTG 021 3
- ACTG 039 6
- ACTG 045 8
- ACTG 051 9
- ACTG 063 11
- ACTG 066 13
- ACTG 073 14
- ACTG 076 16
- ACTG 081 18
- ACTG 084 21
- ACTG 093 22
- ACTG 095 24
- ACTG 096 26
- ACTG 100 27
- ACTG 113 29

ACTG 116 30
ACTG 117 33
ACTG 118 36
ACTG 120 39
ACTG 128 41
ACTG 134 43
AI455-003 45
BUCRC 002 46
C89-258 48
FDA 11A 50
FDA 12C 51
FDA 31B 53
FDA 39A 54
FDA 39C 56
FDA 40A 57
FDA 4G 59
N3300 60
NS 401 62
NS 402 63
TX 301 65
Glossary 66
Order Form 73

FINDING INFORMATION IN THIS DIRECTORY

Cross-References

The main body of this directory is in order of protocol number, which appears in the upper right corner of the page at the start of each protocol entry. Before the main body of information there are four cross-reference lists to help you locate specific protocols alphabetically by DIAGNOSIS, DRUG, DRUG TYPE, and LOCATION. There is also a cross reference list for treatment INDs and open label protocols.

If you wish to look up protocols for people with ARC, for example, first find ARC in the DIAGNOSIS/PROTOCOL CROSS REFERENCE. The entries for ARC point to several specific clinical trials, each of which is listed with its page number. Similarly, you can locate all the clinical trials in Worcester, at University of Massachusetts Medical Center, by checking the LOCATION/PROTOCOL CROSS REFERENCE; or all trials for the drug ddI by consulting the DRUG/PROTOCOL CROSS REFERENCE; or protocols for immunomodulating drugs by looking in the DRUG TYPE/PROTOCOL CROSS REFERENCE.

Protocol Information

The information for each clinical trial or protocol is presented under the following headings (refer to SAMPLE protocol):

1. **Protocol number:** An indentifying number assigned to the study by the researchers.
2. **Sponsor:** The name of the drug company or institution paying for the study.
3. **Phase:** A number to indicate whether the study is a phase 1, 2, or 3 protocol. Treatment INDs are indicated by 'IND' and open label studies will have 'Openlbl' in this field.
4. **Title:** A brief description of the study.
5. **Objective:** The goal of the study.
6. **Drug type:** The general category of the drug being studied, such as ANTIVIRAL or IMMUNOMODULATOR.
7. **Placebo flag:** A yes or no to indicate whether the trial is placebo-controlled.
8. **Inpatient flag:** A yes or no to indicate whether the protocol will require any period of hospitalization of the participants.
9. **Drug:** The name of the drug being tested.
10. **Dose:** The amount and frequency of the drug to be given, for example, 200 mg q 4 or 200 milligrams four times per day.
11. **Route:** The means by which the drug is administered, for example, PO (orally) or IV (intravenously).

12. **Duration:** The length of the clinical trial, usually in units of weeks. (N.B. Drug, dose, route, and duration may occur more than once, depending on the number of drugs or combinations of drugs being tested. The directory allows for up to four sets of drug information. In the case of protocols with more than four "arms", the additional information will be found under "Other Information" at the bottom of the protocol entry.)
13. **Inclusion Criteria:** The principal requirements or conditions that candidates must meet to be included in the trial. Up to five may be listed.
14. **Exclusion Criteria:** Ages and conditions that disqualify candidates from the trial. Up to five criteria may be listed.
15. **Location Information:** The names and phone numbers of institutions and contact persons for the clinical trial. Multiple locations may appear. Information relative to the status of the trial occurs with each location.
16. **Diagnosis:** The diagnosis group for which the trial is intended. Multiple diagnoses may be listed.
17. **Other Information:** Any miscellaneous information about the protocol which does not belong under the above headings.

The information presented for each protocol is distilled from a much larger body of information. If you wish to obtain more detailed information about any particular clinical trial, you should contact the protocol nurse or coordinator whose name and telephone number appear under "Location Information."

Please refer to the Glossary at the end of the directory for explanations of medical and technical terms.

A Note on "Expanded Access"

Included within is information on experimental treatments which are available outside of clinical trials. The ddI protocols listed on pages 54, 56, and 57, for example, are intended to make ddI available either as a treatment IND (investigational new drug) or on a "compassionate use" basis for persons who may benefit from the drug but who do not meet the criteria for inclusion in a clinical trial. Because the so-called "expanded access" system enables treatment and monitoring of patients to take place in the physician's office, patients who live far away from hospitals or research facilities where clinical trials are conducted may also gain access to experimental therapies. Besides ddI, there are expanded-access protocols for erythropoietin, spiramycin, fluconazole, ddC, and trimetrexate/leucovorin. Please refer to the cross reference table on page xiv for a listing of these protocols.

SAMPLE LISTING

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

1. ***Protocol:*** XYZ 2. ***Sponsor:*** ABC Company 3. ***Phase:*** 1

4. ***Title:*** Sample Protocol

5. ***Objective:*** To illustrate Directory format

6. ***Drug Type:*** Sample drug type 7. ***Placebo:*** N 8. ***Inpatient:*** N
9. ***Drug:*** Sample drug 10. ***Dose:*** 200 mg q4
11. ***Route:*** PO
12. ***Duration:*** 52 weeks

Inclusion Criteria

13.
1. Inclusion criterion 1
2. Inclusion criterion 2
3. Inclusion criterion 3
4. Inclusion criterion 4
5. Inclusion criterion 5

Exclusion Criteria

14.
Age < 12 ***Age*** > 70
1. Exclusion criterion 1
2. Exclusion criterion 2
3. Exclusion criterion 3
4. Exclusion criterion 4
5. Exclusion criterion 5

Location Information

15.
Sample institution, Boston, MA 02111
Nurse:
Coordinator:
Physician Contact:
Status: Open ***Open Date:*** 01/01/90 ***Close Date:*** / /

16. ***Diagnosis:*** AIDS

Other Information

17. Other information regarding this protocol

* * * * * * * * * *

DIAGNOSIS/PROTOCOL CROSS REFERENCE

Diagnosis	Drug	Protocol	Page
AIDS	ddI/AZT	01, Project P53	1
AIDS	Bactrim	ACTG 021	3
AIDS	AZT/Acyclovir	ACTG 063	11
AIDS	rsT4	ACTG 066	13
AIDS	AZT/AP/Dapsone/Bactrim	ACTG 081	18
AIDS	AZT/Alpha-2A-IFN	ACTG 096	26
AIDS	DNJ	ACTG 100	27
AIDS	Spiramycin	ACTG 113	29
AIDS	ddI/AZT	ACTG 116	30
AIDS	ddI/AZT	ACTG 117	33
AIDS	ddI	ACTG 118	36
AIDS	Itraconazole	ACTG 120	39
AIDS	AZT/rCD4-IgG	ACTG 134	43
AIDS	d4T	AI455-003	45
AIDS	ddC	FDA 31B	53
AIDS	ddI	FDA 39A	54
AIDS	ddI	FDA 39C	56
AIDS	ddI	FDA 40A	57
AIDS	EPO	FDA 4G	59
AIDS	ddC/AZT	N3300	60
AIDS neurologic	ddI	FDA 39A	54
AIDS neurologic	ddI	FDA 39C	56
ARC	AZT/ddI	01, Project P53	1
ARC	rsT4	ACTG 066	13
ARC	AZT/AP/Dapsone/Bactrim	ACTG 081	18
ARC	DNJ	ACTG 100	27
ARC	ddI/AZT	ACTG 116	30
ARC	ddI/AZT	ACTG 117	33
ARC	ddI	ACTG 118	36
ARC	AZT/rCD4-IgG	ACTG 134	43
ARC	d4T	AI455-003	45
ARC	ddC	FDA 31B	53
ARC	ddC/AZT	N3300	60
Asymptomatic	AZT/rCD4-IgG	ACTG 134	43
CMV	Ganciclovir/GM-CSF	ACTG 073	14
CMV	Foscarnet	ACTG 093	22
HIV-	AZT	NS 402	63

Diagnosis	Drug	Protocol	Page
HIV+	ddI/AZT	01, Project P53	1
HIV+	THF-Gamma 2/AZT	BUCRC 002	46
Immunocompromised	Spiramycin	FDA 11A	50
KS	AZT/Alpha-2A-IFN	ACTG 096	26
OI	Bactrim	ACTG 021	3
OI	AZT/Acyclovir	ACTG 063	11
OI	Ganciclovir/GM-CSF	ACTG 073	14
OI	Itraconazole	ACTG 084	21
OI	Foscarnet	ACTG 093	22
OI	Foscarnet/Vidarabine	ACTG 095	24
OI	Spiramycin	ACTG 113	29
OI	Itraconazole	ACTG 120	39
OI	SCH 39304	C89-258	48
OI	Fluconazole	FDA 12C	51
OI	ddI	FDA 39A	54
OI	ddI	FDA 39C	56
OI	ddC/AZT	N3300	60
PCP	AZT/ddI	01, Project P53	1
PCP	Trimetrexate/Leucovorin	ACTG 039	6
PCP	ddC/AZT	N3300	60
PCP	Trimetrexate/Leucovorin	NS 401	62
PCP	Trimetrexate/Leucovorin	TX 301	65
Pediatric AIDS/ARC	IVIG	ACTG 045	8
Pediatric AIDS/ARC	IVIG/AZT	ACTG 051	9
Pediatric HIV infx	AZT	ACTG 128	41
Perinatal HIV infx	AZT	ACTG 076	16

DRUG/PROTOCOL CROSS REFERENCE

Drug	Protocol	Page
Acyclovir/AZT	ACTG 063	11
Aerosol Pentamidine/Bactrim/AZT	ACTG 021	3
Aerosol Pentamidine/Bactrim/Dapsone	ACTG 081	18
Alpha-2A-IFN/AZT	ACTG 096	26
AZT	ACTG 076	16
AZT	ACTG 128	41
AZT	NS 402	63
AZT/Acyclovir	ACTG 063	11
AZT/Aerosol Pentamidine/Bactrim/Dapsone	ACTG 081	18
AZT/Alpha-2A-IFN	ACTG 096	26
AZT/ddC	N3300	60
AZT/ddI	01, Project P53	1
AZT/ddI	ACTG 116	30
AZT/ddI	ACTG 117	33
AZT/Intravenous Gammaglobulin(IVIG)	ACTG 051	9
AZT/rCD4-IgG	ACTG 134	43
Bactrim/Aerosol Pentamidine/AZT	ACTG 021	3
d4T	AI455-003	45
ddC	FDA 31B	53
ddC/AZT	N3300	60
ddI	FDA 39A	54
ddI	FDA 39C	56
ddI	FDA 40A	57
ddI	ACTG 118	36
ddI/AZT	01, Project P53	1
ddI/AZT	ACTG 116	30
ddI/AZT	ACTG 117	33

Drug	Protocol	Page
Erythropoietin(EPO)	FDA 4G	59
Fluconazole	FDA 12C	51
Foscarnet	ACTG 093	22
Foscarnet/Vidarabine	ACTG 095	24
Ganciclovir/GM-CSF	ACTG 073	14
Intravenous Gammaglobulin(IVIG)	ACTG 045	8
Intravenous Gammaglobulin(IVIG)/AZT	ACTG 051	9
Itraconazole	ACTG 084	21
Itraconazole	ACTG 120	39
Leucovorin/Trimetrexate	ACTG 039	6
Leucovorin/Trimetrexate	NS 401	62
Leucovorin/Trimetrexate	TX 301	65
N Butyl Deoxnojirimycin(DNJ)	ACTG 100	27
rsT4	ACTG 066	13
SCH 39304	C89-258	48
Spiramycin	ACTG 113	29
Spiramycin	FDA 11A	50
THF-Gamma 2/AZT	BUCRC 002	46
Trimethoprim-Sulfamethoxazole(Bactrim)/AP/AZT	ACTG 021	3
Trimetrexate/Leucovorin	ACTG 039	6
Trimetrexate/Leucovorin	NS 401	62
Trimetrexate/Leucovorin	TX 301	65
Vidarabine/Foscarnet	ACTG 095	24

DRUG TYPE/PROTOCOL CROSS REFERENCE

Drug Type	Drug	Protocol	Page
Antifungal	AP/ T/S (Bactrim)	ACTG 021	3
Antifungal	Fluconazole	FDA 12C	51
Antifungal	Itraconazole	ACTG 084	21
Antifungal	Itraconazole	ACTG 120	39
Antifungal	SCH 39304	C89-258	48
Antifungal	Trimetrexate	ACTG 039	6
Antifungal	Trimetrexate	NS 401	62
Antifungal	Trimetrexate	TX 301	65
Antifungal/Antiviral	AP/ T/S /Dapsone/AZT	ACTG 081	18
Antiparasitic	Spiramycin	ACTG 113	29
Antiparasitic	Spiramycin	FDA 11A	50
Antiviral	AZT	ACTG 063	11
Antiviral	AZT	ACTG 076	16
Antiviral	AZT	ACTG 128	41
Antiviral	AZT	ACTG 134	43
Antiviral	AZT	NS 402	63
Antiviral	Foscarnet	ACTG 093	22
Antiviral	Foscarnet/Vidarabine	ACTG 095	24
Antiviral	IVIG	ACTG 045	8
Antiviral	IVIG/AZT	ACTG 051	9
Antiviral	N Butyl Deoxnojirimycin	ACTG 100	27
Antiviral	d4T	AI455-003	45
Antiviral	ddC	FDA 31B	53
Antiviral	ddC/AZT	N3300	60
Antiviral	ddI	ACTG 118	36
Antiviral	ddI	FDA 39A	54
Antiviral	ddI	FDA 39C	56
Antiviral	ddI	FDA 40A	57
Antiviral	ddI/AZT	ACTG 116	30
Antiviral	ddI/AZT	ACTG 117	33
Antiviral	rsT4	ACTG 066	13
Antiviral/Chemotherapy	AZT/Alpha-2A-IFN	ACTG 096	26
Antiviral/Immunomod	AZT/THF-Gamma 2	BUCRC 002	46
Antiviral/Immunomod	Ganciclovir/GM-CSF	ACTG 073	14

LOCATION/PROTOCOL CROSS REFERENCE

The following abbreviations have been used to designate institutions:

BMC	Baystate Medical Center
BIH	Beth Israel Hospital
BCH	Boston City Hospital
BUMC	Boston University Medical Center
BWH	Brigham and Women's Hospital
BUCRC	Brown Univerity Clinical Research Center
CH	Children's Hospital
MGH	Massachusetts General Hospital
NEDH	New England Deaconess Hospital
NEMC	New England Medical Center
RWGH	Roger Williams General Hospital
UMMC	University of Massachusetts Medical Center

City	Institution	Protocol	Drug	Page
Boston	BIH	ACTG 021	AP/AZT/Bactrim	3
Boston	BIH	ACTG 039	Trimetrexate/Leucovorin	6
Boston	BIH	ACTG 063	Acyclovir/AZT	11
Boston	BIH	ACTG 073	Ganciclovir/GM-CSF	14
Boston	BIH	ACTG 081	AP/AZT/Bactrim/Dapsone	18
Boston	BIH	ACTG 093	Foscarnet	22
Boston	BIH	ACTG 095	Foscarnet/Vidarabine	24
Boston	BIH	ACTG 116	ddI/AZT	30
Boston	BIH	ACTG 117	ddI/AZT	33
Boston	BIH	ACTG 118	ddI	36
Boston	BCH	ACTG 021	AP/AZT/Bactrim	3
Boston	BCH	ACTG 045	IVIG	8
Boston	BCH	ACTG 051	IVIG/AZT	9
Boston	BCH	ACTG 063	AZT/Acyclovir	11
Boston	BCH	ACTG 076	AZT	16
Boston	BCH	ACTG 081	AP/AZT/Bactrim/Dapsone	18
Boston	BCH	ACTG 093	Foscarnet	22
Boston	BCH	ACTG 116	ddI/AZT	30
Boston	BCH	ACTG 117	ddI/AZT	33
Boston	BCH	ACTG 118	ddI	36
Boston	BCH	ACTG 128	AZT	41
Boston	BUMC	C89-258	SCH 39304	48
Boston	BWH	ACTG 076	AZT	16

City	Institution	Protocol	Drug	Page
Boston	CH	ACTG 051	IVIG/AZT	9
Boston	CH	ACTG 128	AZT	41
Boston	MGH	ACTG 039	Trimetrexate/Leucovorin	6
Boston	MGH	ACTG 063	Acyclovir/AZT	11
Boston	MGH	ACTG 066	rsT4	13
Boston	MGH	ACTG 081	AP/AZT/Bactrim/Dapsone	18
Boston	MGH	ACTG 093	Foscarnet	22
Boston	MGH	ACTG 095	Foscarnet/Vidarabine	24
Boston	MGH	ACTG 100	DNJ	27
Boston	MGH	ACTG 116	ddI/AZT	30
Boston	MGH	ACTG 117	ddI/AZT	33
Boston	MGH	ACTG 118	ddI	36
Boston	NEDH	ACTG 021	AP/AZT/Bactrim	3
Boston	NEDH	ACTG 039	Trimetrexate/Leucovorin	6
Boston	NEDH	ACTG 081	AP/AZT/Bactrim/Dapsone	18
Boston	NEDH	ACTG 116	ddI/AZT	30
Boston	NEDH	ACTG 117	ddI/AZT	33
Boston	NEDH	ACTG 118	ddI	36
Boston	NEMC	01, Project P53	ddI/AZT	1
Boston	NEMC	N3300	ddC/AZT	60
Providence, RI	BUCRC	BUCRC 002	THF-Gamma 2	46
Providence, RI	RWGH	AI455-003	d4T	45
Springfield	BMC	ACTG 021	AP/AZT/Bactrim	3
Springfield	BMC	ACTG 116	ddI/AZT	30
Springfield	BMC	ACTG 117	ddI/AZT	33
Springfield	BMC	ACTG 118	ddI	36
Springfield	BMC	ACTG 128	AZT	41
Worcester	UMMC	ACTG 021	AP/AZT/Bactrim	3
Worcester	UMMC	ACTG 039	Trimetrexate/Leucovorin	6
Worcester	UMMC	ACTG 051	IVIG/AZT	9
Worcester	UMMC	ACTG 063	Acyclovir/AZT	11
Worcester	UMMC	ACTG 081	AP/AZT/Bactrim/Dapsone	18
Worcester	UMMC	ACTG 084	Itraconazole	21
Worcester	UMMC	ACTG 096	Alpha-2A-IFN/AZT	26
Worcester	UMMC	ACTG 113	Spiramycin	29
Worcester	UMMC	ACTG 116	ddI/AZT	30

City	Institution	Protocol	Drug	Page
Worcester	UMMC	ACTG 117	ddI/AZT	33
Worcester	UMMC	ACTG 118	ddI	36
Worcester	UMMC	ACTG 120	Itraconazole	39
Worcester	UMMC	ACTG 128	AZT	41
Worcester	UMMC	ACTG 134	rCD4-IgG	43
USA		FDA 4G	Erythropoietin	59
USA		FDA 11A	Spiramycin	50
USA		FDA 12C	Fluconazole	51
USA		FDA 31B	ddC	53
USA		FDA 39A	ddI	54
USA		FDA 39C	ddI	56
USA		FDA 40A	ddI	57
USA		NS 401	Trimetrexate/Leucovorin	62
USA		NS 402	AZT	63
USA		TX 301	Trimetrexate/Leucovorin	65

TREATMENT INDs AND OPEN LABEL PROTOCOLS

Protocol	Drug	Page
FDA 4G	Erythropoietin	59
FDA 11A	Spiramycin	50
FDA 12C	Fluconazole	51
FDA 31B	ddC	53
FDA 39A	ddI	54
FDA 39C	ddI	56
FDA 40A	ddI	57
NS 401	Trimetrexate/Leucovorin	62
NS 402	AZT	63
TX 301	Trimetrexate/Leucovorin	65

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Protocol: 01, Project P53 ***Sponsor:*** Burroughs-Wellc ***Phase:*** 1

Title: Concurrent AZT and ddI therapy for HIV-infected persons

Objective: Determine safety and dosing of combination AZT and ddI

Drug Type: Antiviral ***Placebo:*** N ***Inpatient:*** N
Drug: ddI ***Dose:*** 45/167/250 mg q12h
Route: PO
Duration: 24 weeks

Drug: AZT ***Dose:*** 50/100/200 mg q8h
Route: PO
Duration: 24 weeks

Inclusion Criteria

1. HIV+
2. < 400 CD4
3. > 1200 neutrophils
4. > 9.0 Hemoglobin
5. > 90,000 platelets

Exclusion Criteria

Age < 18
1. Previous ddI therapy
2. CNS toxoplasmosis or cryptococcosis
3. Previous AZT for more than 120 days
4. Seizure disorder
5. Pancreatitis

Location Information

New England Medical Center, Boston, MA 02111
Nurse: Marca Wilk (617)956-5114*
Coordinator:
Physician Contact: Paul Skolnik (617)956-7008
Status: Open ***Open Date:*** 01/01/90 ***Close Date:*** / /

Diagnosis: AIDS ARC HIV+ PCP

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Other Information

* beeper no. 1267

* * * * * * * * * * *

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Protocol: ACTG 021 ***Sponsor:*** NIAID ***Phase:*** 3

Title: Trial to compare Trimethoprim-sulfamethoxazole (T/S) vs aerosolized pentamidine for PCP prophylaxis

Objective: Comparison of two methods of PCP prophylaxis in patients with AIDS

Drug Type: Antifungal/Antiviral ***Placebo:*** N ***Inpatient:*** N
Drug: T/S (Bactrim) ***Dose:*** 160 mg T; 800 mg S qd
Route: PO
Duration: 52 weeks

Drug: Pentamidine ***Dose:*** 300 mg/month
Route: aerosol
Duration: 52 weeks

Drug: AZT ***Dose:*** 100 mg q4 (600 mg/day)
Route: PO
Duration: 52 weeks

Inclusion Criteria

1. Successful treatment of PCP within previous 10 weeks
2. Ability to tolerate T/S, AP
3. Acceptable hematologic and chemistry parameters

Exclusion Criteria

Age < 12
1. Drug hypersensitivity
2. Pregnancy or breast-feeding
3. Prior prophylaxis between acute episode and enrollment
4. G-G-PD deficiency

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Location Information

Beth Israel Hospital, Boston, MA 02215
Nurse: Sheila Hussey (617)732-4103
Coordinator: Ellen Godfrey (617)726-5596
Physician Contact: Clyde Crumpacker (617)735-6661
Status: Open ***Open Date:*** 04/01/90 ***Close Date:*** 09/01/90

Boston City Hospital, Boston, MA 02118
Nurse: ( ) -
Coordinator: Carol Saunders (617)534-5404
Physician Contact: Howard Liebman (617)534-4800
Status: Open ***Open Date:*** 04/01/90 ***Close Date:*** / /

New England Deaconess Hospital, Boston, MA 02215
Nurse: Helen Fitch (617)732-9729
Coordinator: Ellen Godfrey (617)726-5596
Physician Contact: J. Davis Allan (617)732-9480
Status: Open ***Open Date:*** 04/01/90 ***Close Date:*** 09/01/90

Baystate Medical Center, Springfield, MA 01199
Nurse: Susan Oaks (413)784-5376
Coordinator: Charla Andrews (508)856-2456
Physician Contact: Michael Sands (413)784-5376
Status: Open ***Open Date:*** / / ***Close Date:*** 09/01/90

University of Mass. Medical Center, Worcester, MA 01655
Nurse:
Coordinator: Charla Andrews (508)856-2456
Physician Contact: Sarah Cheeseman (508)856-2456
Status: Open ***Open Date:*** 01/12/89 ***Close Date:*** 09/01/90

Diagnosis: AIDS OI

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Other Information

All Patients will receive AZT as well as be randomized to one of the 2 prophylactic regimens. Patients who develop severe adverse reaction will be offered continued AZT and alternative PCP prophylaxis. Patients who develop intolerance to AZT may receive may receive ddI via expanded access while on this protocol.

* * * * * * * * * *

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Protocol: ACTG 039 ***Sponsor:*** NIAID ***Phase:*** IND

Title: Open prospective study of TMTX with LCV rescue for patients with PCP and serious intolerance to approved therapies

Objective: Assess safety/efficacy of TMTX/LCV in PCP patients intolerant of or not responding to other therapies

Drug Type: Antifungal ***Placebo:*** N ***Inpatient:*** N
Drug: Trimetrexate ***Dose:*** 45 mg/m2 qd
Route: IV
Duration: 21 days

Drug: Leucovorin ***Dose:*** 30 mg/m2 q6h
Route: PO, IV
Duration: 24 days

Inclusion Criteria

1. PCP confirmed
2. Intolerance to Bactrim and Pentamidine
3. BP > 90 mm Hg

Exclusion Criteria

Age < 12
1. Unacceptable chemistry, hemotologic laboratory parameters

Location Information

Beth Israel Hospital, Boston, MA 02215
Nurse: Sheila Hussey (617)735-4103
Coordinator: Ellen Godfrey (617)726-5596
Physician Contact: Clyde Crumpacker (617)735-3661
Status: Open ***Open Date:*** 04/01/88 ***Close Date:*** / /

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Massachusetts General Hospital, Boston, MA 02114
Nurse: Teri Flynn (617)726-3814
Coordinator: Ellen Godfrey (617)726-5596
Physician Contact: Martin Hirsch (617)726-3812
Status: Open ***Open Date:*** 01/01/88 ***Close Date:*** / /

New England Deaconess Hospital, Boston, MA 02215
Nurse: Helen Fitch (617)732-9729
Coordinator: Ellen Godfrey (617)726-5596
Physician Contact: J. Davis Allan (617)732-9480
Status: Open ***Open Date:*** 04/01/88 ***Close Date:*** / /

University of Mass. Medical Center, Worcester, MA 01655
Nurse:
Coordinator: Charla Andrews (508)856-2456
Physician Contact: Sarah Cheeseman (508)856-2456
Status: Open ***Open Date:*** 04/01/88 ***Close Date:*** / /

Diagnosis: PCP

Other Information

Compassionate use considered case by case; not a referral-type protocol but intended as a rescue for patients already hospitalized with PCP.

* * * * * * * * * * *

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Protocol: ACTG 045 ***Sponsor:*** NICHD ***Phase:*** 2

Title: A clinical trial of intravenous immunoglobulin (IVIG) for children with symptomatic HIV infection

Objective: Determine whether monthly IVIG, compared to placebo, will reduce life-threatening bacterial infections in HIV-infected children

Drug Type: Antiviral ***Placebo:*** Y ***Inpatient:*** N
Drug: IVIG ***Dose:*** 400 mg/kg q4 weeks
Route: IV
Duration: 104 weeks

Drug: Albumin (Placebo) ***Dose:*** 400 mg/kg q4 weeks
Route: IV
Duration: 104 weeks

Inclusion Criteria

1. Symptomatic HIV infection in children who are HIV positive
2. >200 CD4 and P-1-B or P-2-A or P-2-B or P-2-C or P-2-D-3 or P-2-F
3. Non-hemophiliac

Exclusion Criteria

Age > 13

1. Asymptomatic with normal or unknown immune function
2. Hypogammaglobulinemia
3. ITP requiring IVIG
4. Antiviral therapy with AZT only
5. < 200 CD4 and/or P-2-D-1, P-2-D-2

Location Information

Boston City Hospital, Boston, MA 02118
Nurse: Anne Marie Regan (617)534-5813
Coordinator: Anne Marie Regan (617)534-5813
Physician Contact: Ellen Cooper (617)534-5588
Status: Open ***Open Date:*** 03/01/88 ***Close Date:*** / /

Diagnosis: Pediatric AIDS/ARC

* * * * * * * * * * *

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Protocol: ACTG 051 ***Sponsor:*** NIAID ***Phase:*** 3

Title: Double-blinded placebo-controlled trial to evaluate IVIG in children with symptomatic HIV infection who are receiving AZT

Objective: Assess safety and efficacy of AZT and IVIG vs AZT and placebo

Drug Type: Antiviral ***Placebo:*** Y ***Inpatient:*** N
Drug: IVIG ***Dose:*** 400 mg/kg
Route: IV
Duration: 100 weeks

Drug: AZT ***Dose:*** 180 mg/m2 q6h
Route: PO
Duration: 100 weeks

Drug: Albumin (placebo) ***Dose:*** 400 mg/kg
Route: IV
Duration: 100 weeks

Inclusion Criteria

1. Children with AIDS or ARC
2. Failure to thrive
3. No acute opportunistic infection

Exclusion Criteria

Age > 12

1. Lymphoproliferative disease as sole evidence of HIV
2. Treatment withother antiretrovirals within 4 weeks
3. Treatment with immunomodulating agents within 4 weeks
4. Treatment with immunoglobulin within 4 weeks
5. Hypersensitivity to immunoglobulin

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Location Information

Boston City Hospital, Boston, MA 02118
Nurse: Anne Marie Regan (617)534-5813
Coordinator: Anne Marie Regan (617)534-5813
Physician Contact: Stephen Pelton (617)534-5506
Status: Open ***Open Date:*** 12/01/88 ***Close Date:*** 09/01/90

Children's Hospital, Boston, MA 02215
Nurse: Andrea Rubin (617)735-7879
Coordinator: Kerrie Liebendorfer (617)735-8198
Physician Contact: Lynn Luginbuhl (617)735-6832
Status: Open ***Open Date:*** 12/01/88 ***Close Date:*** 09/01/90

University of Mass. Medical Center, Worcester, MA 01655
Nurse: Amy Sharples (508)856-3947
Coordinator: Charla Andrews (508)856-2456
Physician Contact: John Sullivan (508)856-3947
Status: Open ***Open Date:*** 12/01/88 ***Close Date:*** 09/01/90

Diagnosis: Pediatric AIDS/ARC

* * * * * * * * * *

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Protocol: ACTG 063 ***Sponsor:*** NIAID ***Phase:*** 2/3

Title: Double-blind comparative study of AZT vs AZT and Acyclovir as treatment for patients with AIDS

Objective: Assess whether combined therapy of AZT and Acyclovir is more effective than AZT alone

Drug Type: Antiviral ***Placebo:*** Y ***Inpatient:*** N
Drug: AZT ***Dose:*** 100 mg q4h (500 mg/day)
Route: PO
Duration: 104 weeks

Drug: Acyclovir ***Dose:*** 800 mg q4h
Route: PO
Duration: 104 weeks

Inclusion Criteria

1. First episode of PCP or other OI within 120 days
2. AIDS defined by OI (CDC group IV C-1)
3. Acceptable hematologic and chemistry parameters

Exclusion Criteria

Age < 12
1. Systemic or progressive KS
2. Active OI
3. More than 8 weeks treatment with AZT
4. Chronic Acyclovir therapy
5. 'Constitutional Disease' or neuro. disease as sole AIDS condition

Location Information

Beth Israel Hospital, Boston, MA 02215
Nurse: Sheila Hussey (617)735-4103
Coordinator: Ellen Godfrey (617)726-5596
Physician Contact: Clyde Crumpacker (617)735-3661
Status: Open ***Open Date:*** 02/01/89 ***Close Date:*** / /

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Boston City Hospital, Boston, MA 02118
Nurse: ( ) -
Coordinator: Carol Saunders (617)534-5404
Physician Contact: Timothy Cooley (617)534-4385
Status: Open ***Open Date:*** 10/20/89 ***Close Date:*** / /

Massachusetts General Hospital, Boston, MA 02114
Nurse: Teri Flynn (617)726-3819
Coordinator: Ellen Godfrey (617)726-5596
Physician Contact: Martin Hirsch (617)726-3812
Status: Open ***Open Date:*** 01/01/89 ***Close Date:*** / /

University of Mass. Medical Center, Worcester, MA 01655
Nurse:
Coordinator: Charla Andrews (508)856-2456
Physician Contact: Sarah Cheeseman (508)856-3158
Status: Open ***Open Date:*** 01/15/89 ***Close Date:*** / /

Diagnosis: AIDS OI

Other Information

Placebo applies only in relation to acyclovir. Patients will be randomly assigned to either AZT and Acyclovir or AZT and placebo.

* * * * * * * * * *

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Protocol: ACTG 066 ***Sponsor:*** NIAID ***Phase:*** 1

Title: Dose tolerance trial of recombinant soluble CD4

Objective: Assess safety of administration of RST4 for AIDS and ARC patients

Drug Type: Antiviral ***Placebo:*** N ***Inpatient:*** Y
Drug: rsT4 ***Dose:*** 30 mg/day and higher
Route: IM
Duration: 12 weeks

Inclusion Criteria

1. < 250 CD4
2. AIDS or ARC diagnosis
3. p24 antigen positive

Exclusion Criteria

Age < 12
1. AIDS dementia
2. Malignancy other than KS
3. Active OI
4. Pre-existing antibodies to rCD4

Location Information

Massachusetts General Hospital, Boston, MA 02114
Nurse: Teri Flynn (617)726-3819
Coordinator: Ellen Godrey (617)726-5596
Physician Contact: Robert Schooley (617)726-3812
Status: Open ***Open Date:*** 09/12/88 ***Close Date:*** / /

Diagnosis: AIDS ARC

Other Information

For a subset of Patients, one overnight stay may be required to obtain pharmacokinetic data.

* * * * * * * * * * *

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Protocol: ACTG 073 ***Sponsor:*** NIAID ***Phase:*** 2

Title: Randomized Phase Two study of GM-CSF* and Ganciclovir versus Ganciclovir to treat sight-threatening CMV retinitis

Objective: Determine the effect of GM-CSF on modulation of the granulocytopenia associated with Ganciclovir therapy

Drug Type: Antiviral/Immunomod ***Placebo:*** N ***Inpatient:*** Y
Drug: Ganciclovir ***Dose:*** 5 mg/kg q12h or /day
Route: IV
Duration: 16 weeks

Drug: GM-CSF ***Dose:*** titrated
Route: subcutaneous
Duration: 16 weeks

Inclusion Criteria

1. Sight-threatening CMV retinitis infection
2. HIV infection
3. Acceptable hematologic and chemistry parameters

Exclusion Criteria

Age < 12 ***Age*** > 65
1. Pregnancy or breast-feeding
2. Concurrent acyclovir, Foscarnet, Bactrim

Location Information

Beth Israel Hospital, Boston, MA 02215
Nurse: Jocelyn Loftus (617)735-5942
Coordinator: Ellen Godfrey (617)726-5596
Physician Contact: Clyde Crumpacker (617)735-3661
Status: Open ***Open Date:*** 07/01/89 ***Close Date:*** / /

Diagnosis: CMV OI

Other Information

*GM-CSF = granulocyte-macrophage colony stimulating factor. Patients are randomized to either combination (GMCSF + GCV) or GCV alone.

* * * * * * * * * *

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Protocol: ACTG 076 ***Sponsor:*** NIAID ***Phase:*** 3

Title: The efficacy, safety and tolerance of AZT in infants with perinatal HIV exposure

Objective: Evaluate safety and pharmacokinetics of AZT in infants

Drug Type: Antiviral ***Placebo:*** Y ***Inpatient:*** N
Drug: AZT ***Dose:*** 3 mg/kg
Route: PO
Duration: to 6 weeks

Inclusion Criteria

1. Born to mothers infected with HIV
2. 24 hours or younger
3. Gestational age 36-42 weeks
4. Birth weight 2,000 grams or greater
5. Parent/guardian able to give informed consent

Exclusion Criteria

1. Have been breast-fed
2. Have received blood products or extra drug therapy
3. Require drug therapy for drug or alcohol withdrawal
4. Need treatment for bilirubinemia
5. Serious, non-HIV medical conditions

Location Information

Boston City Hospital, Boston, MA 02118
Nurse: Anne Marie Regan (617)534-5813
Coordinator: Anne Marie Regan (617)534-5813
Physician Contact: Stephen Pelton (617)534-5506
Status: T/B/A ***Open Date:*** / / ***Close Date:*** / /

Brigham and Women's Hospital, Boston, MA 02215
Nurse: Kerrie Liebendorfer (617)735-8198
Coordinator: Kerrie Liebendorfer (617)735-8198
Physician Contact: Kenneth McIntosh (617)735-7621
Status: T/B/A ***Open Date:*** / / ***Close Date:*** / /

Diagnosis: Perinatal HIV infx

Other Information

The open date of this study is to be announced.

* * * * * * * * * * *

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Protocol: ACTG 081 ***Sponsor:*** NIAID ***Phase:*** 3

Title: Randomized trial of 3 anti-PCP agents plus AZT for primary prevention of serious infection in patients with advanced HIV

Objective: Assess efficacy of combination of AZT and 1 of 3 primary prophylaxes

Drug Type: Antiviral/Antifungal ***Placebo:*** N ***Inpatient:*** N
Drug: AZT ***Dose:*** 100 mg q4h
Route: PO
Duration: 30 months

Drug: Pentamidine ***Dose:*** 300 mg/month
Route: aerosol
Duration: 30 months

Drug: Dapsone ***Dose:*** 50 mg/day
Route: PO
Duration: 30 months

Drug: Bactrim/Septra ***Dose:*** 1 DS tab bid
Route: PO
Duration: 30 months

Inclusion Criteria

1. < 200 CD4
2. No prior PCP or toxoplasmosis
3. Acceptable hematologic and chemistry parameters
4. Ability to tolerate AZT

Exclusion Criteria

Age < 12
1. Allergy to study medication
2. Treatment for active OI
3. Pregnancy or breast-feeding
4. Active substance abuse

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Location Information

Beth Israel Hospital, Boston, MA 02215
Nurse: Sheila Hussey (617)735-4103
Coordinator: Ellen Godfrey (617)726-5596
Physician Contact: Clyde Crumpacker (617)735-3661
Status: Closed ***Open Date:*** 12/13/89 ***Close Date:*** 06/01/90

Boston City Hospital, Boston, MA 02118
Nurse: Carol Saunders (617)534-5404
Coordinator: Ellen Godfrey (617)726-5596
Physician Contact: Timothy Cooley (617)534-4385
Status: Closed ***Open Date:*** 10/30/89 ***Close Date:*** 06/01/90

Massachusetts General Hospital, Boston, MA 02114
Nurse: Teri Flynn (617)726-3819
Coordinator: Ellen Godfrey (617)726-5596
Physician Contact: Martin Hirsch (617)726-3812
Status: Closed ***Open Date:*** 07/14/89 ***Close Date:*** 06/01/90

New England Deaconess Hospital, Boston, MA 02215
Nurse: Helen Fitch (617)732-9853
Coordinator: Ellen Godfrey (617)726-5596
Physician Contact:
Status: Closed ***Open Date:*** 05/15/90 ***Close Date:*** 06/01/90

University of Mass. Medical Center, Worcester, MA 01655
Nurse:
Coordinator: Charla Andrews (508)856-2456
Physician Contact: Sarah Cheeseman (508)856-3158
Status: Closed ***Open Date:*** 05/01/89 ***Close Date:*** 06/01/90

Diagnosis: AIDS ARC

Other Information

This is an unblinded study with treatment cross-overs. Patients will be provided AZT and be randomly assigned to 1 or 3 prophylaxes. Patients developing AZT intolerance will be eligible for ddI via expanded access while continuing in this study.

* * * * * * * * * *

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Protocol: ACTG 084 ***Sponsor:*** NIAID ***Phase:*** 2

Title: Itraconazole for prevention of relapse of histoplasmosis in AIDS patients

Objective: Evaluate oral itraconazole as maintenance therapy for disseminated histoplasmosis

Drug Type: Antifungal ***Placebo:*** N ***Inpatient:*** N
Drug: Itraconazole ***Dose:*** 300 mg/400 mg qd
Route: PO
Duration: 52 weeks

Inclusion Criteria

1. History of primary or secondary acute histoplasmosis

Exclusion Criteria

Age < 12
1. Active histoplasmosis
2. Cental Nervous System histoplasmosis
3. Pregnancy or breast-feeding
4. Allergy to similar drugs

Location Information

University of Mass. Medical Center, Worcester, MA 01655
Nurse:
Coordinator: Charla Andrews (508)856-2456
Physician Contact: Sarah Cheeseman (508)856-3158
Status: Open ***Open Date:*** 11/13/89 ***Close Date:*** / /

Diagnosis: OI

* * * * * * * * * * *

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Protocol: ACTG 093 ***Sponsor:*** NIAID ***Phase:*** 2

Title: Dose-ranging open trial of Foscarnet for AIDS patients with sight-threatening CMV retinitis

Objective: Evaluate the safety and efficacy of Foscarnet for sight-threatening CMV

Drug Type: Antiviral ***Placebo:*** N ***Inpatient:*** Y
Drug: Foscarnet ***Dose:*** 60 mg/kg q8h
Route: IV
Duration: 2 weeks

Drug: Foscarnet ***Dose:*** 120 mg/kg/day
Route: IV
Duration: 10 wks or more

Inclusion Criteria

1. Sight-threatening CMV retinitis
2. Intolerance or failure of Ganciclovir
3. Ineligibility of Ganciclovir based on low WBC or platelets

Exclusion Criteria

Age < 12
1. Concurrent Acyclovir or Nephrotoxins
2. Pregnancy or breast-feeding
3. Prior use of Foscarnet

Location Information

Beth Israel Hospital, Boston, MA 02215
Nurse: Sheila Hussey (617)735-4103
Coordinator: Ellen Godfrey (617)726-5596
Physician Contact: Clyde Crumpacker (617)735-3661
Status: Open ***Open Date:*** 03/28/89 ***Close Date:*** / /

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Boston City Hospital, Boston, MA 02118
Nurse:
Coordinator: Carol Saunders (617)534-5404
Physician Contact: Timothy Cooley (617)534-4385
Status: Closed ***Open Date:*** / / ***Close Date:*** 06/01/90

Massachusetts General Hospital, Boston, MA 02114
Nurse: Teri Flynn (617)726-3819
Coordinator: Ellen Godfrey (617)726-5596
Physician Contact: Martin Hirsch (617)726-3812
Status: Open ***Open Date:*** 03/28/89 ***Close Date:*** / /

Diagnosis: CMV OI

Other Information

Hospitalization is required for a minimum of 3 days.
Patients are randomized to maintenance dose of either 60 or 90 mg/kg/day.

* * * * * * * * * * *

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Protocol: ACTG 095 ***Sponsor:*** NIAID ***Phase:*** 1

Title: Treatment of acyclovir-resistant mucocutaneous herpes virus infections

Objective: Evaluate and compare two treatments for herpes virus infections

Drug Type: Antiviral ***Placebo:*** N ***Inpatient:*** Y
Drug: Foscarnet ***Dose:*** +/-40 mg/kg, q8h*
Route: IV
Duration: 10-21 days

Drug: Vidarabine ***Dose:*** 15 mg/kg qd
Route: IV
Duration: 10-21 days

Inclusion Criteria

1. Documented acyclovir-resistant mucocutaneous HSV infection
2. HIV infection
3. Course of standard acyclovir therapy

Exclusion Criteria

Age < 12 ***Age >*** 65
1. Concurrent ganciclovir
2. Pre-existing neurologic impairment
3. Pregnancy or breast-feeding

Location Information

Beth Israel Hospital, Boston, MA 02215
Nurse: Sheila Hussey (617)735-4103
Coordinator: Ellen Godfrey (617)726-5596
Physician Contact: Clyde Crumpacker (617)735-3661
Status: Open ***Open Date:*** 07/01/89 ***Close Date:*** / /

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Massachusetts General Hospital, Boston, MA 02114
Nurse: Teri Flynn (617)726-3819
Coordinator: Ellen Godfrey (617)726-5596
Physician Contact: Martin Hirsch (617)726-3812
Status: Open ***Open Date:*** 07/01/89 ***Close Date:*** / /

Diagnosis: OI

Other Information

*Adjusted for creatinine clearance
As of 6/90 study was temporarily closed to enrollment. Re-open date to be announced.

* * * * * * * * * * *

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Protocol: ACTG 096 ***Sponsor:*** NIAID ***Phase:*** 2

Title: Study of AZT and recombinant alpha-2A-interferon in the treatment of patients with AIDS-related Kaposi's sarcoma

Objective: Determine the safety and efficacy of combination therapy

Drug Type: Antiviral/Chemo. ***Placebo:*** N ***Inpatient:*** N
Drug: Alpha-2A-IFN ***Dose:*** 18 million units
Route: Subcutaneous
Duration: 52 weeks

Drug: AZT ***Dose:*** 100 mg q4h
Route: PO
Duration: 52 weeks

Inclusion Criteria

1. AIDS with KS
2. > 5 cutaneous lesions
3. Acceptable laboratory parameters

Exclusion Criteria

Age < 12
1. Active opportunistic infection
2. Neurological disease (HIV)
3. Visceral KS
4. Prior interferon therapy
5. Other malignancy

Location Information

University of Mass. Medical Center, Worcester, MA 01655
Nurse:
Coordinator: Charla Andrews (508)865-2456
Physician Contact: Sarah Cheeseman (508)856-3158
Status: Open ***Open Date:*** 07/28/89 ***Close Date:*** / /

Diagnosis: AIDS KS

* * * * * * * * * * *

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Protocol: ACTG 100 ***Sponsor:*** NIAID ***Phase:*** 1

Title: Dose-tolerance of SC48334 (N Butyl-DNJ) in patients with AIDS and advanced ARC

Objective: Determine maximum tolerated dose of N Butyl DNJ

Drug Type: Antiviral ***Placebo:*** Y ***Inpatient:*** Y
Drug: N Butyl Deoxnojirimycin ***Dose:*** Escalating
Route: PO
Duration: up to 4 months

Inclusion Criteria

1. Diagnosis of AIDS or advanced ARC
2. < 300 CD4

Exclusion Criteria

Age < 12
1. Significant diarrhea
2. Active OI
3. Antiretrovirals within 30 days of entry

Location Information

Massachusetts General Hospital, Boston, MA 02114
Nurse: Teri Flynn (617)726-3819
Coordinator: Ellen Godfrey (617)726-5596
Physician Contact: Martin Hirsch (617)726-3812
Status: Open ***Open Date:*** 04/01/89 ***Close Date:*** / /

Diagnosis: AIDS ARC

Other Information

2 days inpatient time will be required.
Patients may use aerosolized pentamidine prophylaxis.
Patients may be eligible to receive the drug for an additional 90 days if there is no toxicity after 30 days.

* * * * * * * * * *

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Protocol: ACTG 113 ***Sponsor:*** NIAID ***Phase:*** 1/2

Title: Intravenous spiramycin for cryptosporidial diarrhea

Objective: Assess the safety and efficacy of intravenous spiramycin

Drug Type: Antiparasitic ***Placebo:*** * ***Inpatient:*** Y
Drug: Spiramycin ***Dose:*** 3.0 to 4.5 MIU q8h
Route: IV
Duration: 11 to 26 days

Inclusion Criteria

1. Diagnosis of AIDS
2. Cryptosporidial diarrhea

Exclusion Criteria

Age < 12
1. Allergy to macrolide antibiotics
2. Pregnancy or breastfeeding
3. Other diarrheal pathogens
4. Active/progressive OI

Location Information

University of Mass. Medical Center, Worcester, MA 01655
Nurse:
Coordinator: Charla Andrews (508)856-2456
Physician Contact: Sarah Cheeseman (508)856-3158
Status: Open ***Open Date:*** 04/10/90 ***Close Date:*** / /

Diagnosis: AIDS OI

Other Information

Dose and duration depend on patient condition.
* Placebo will be administered for 4 days during first 11 days of protocol.

* * * * * * * * * *

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Protocol: ACTG 116 ***Sponsor:*** NIAID ***Phase:*** 2

Title: Comparison of ddI and AZT in therapy of patients with AIDS and ARC

Objective: Compare the safety and efficacy of ddI and AZT for patients with AIDS and ARC who have taken AZT for less than one year

Drug Type: Antiviral ***Placebo:*** Y ***Inpatient:*** N
Drug: ddI ***Dose:*** High and low dose*
Route: PO
Duration: up to 18 months

Drug: AZT ***Dose:*** 100 mg q4h, 600 mg/day
Route: PO
Duration: up to 18 months

Drug: Pentamidine** ***Dose:*** 300 mg/once a month
Route: aerosol
Duration: up to 18 months

Inclusion Criteria

1. AIDS or ARC with 1 or more symptoms and CD4 less than 300
2. Prior AZT use less than 1 year or AZT-naive
3. Acceptable hematologic and chemistry parameters

Exclusion Criteria

Age < 12
1. KS requiring therapy
2. Significant neurologic disease including seizures
3. History of pancreatitis or heart disease
4. Ongoing acute opportunistic infection requiring therapy
5. Elevated serum amylase

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Location Information

Beth Israel Hospital, Boston, MA 02215
Nurse: Sheila Hussey (617)735-4103
Coordinator: Ellen Godfrey (617)726-5596
Physician Contact: Clyde Crumpacker (617)735-3528
Status: Open ***Open Date:*** 10/01/89 ***Close Date:*** / /

Boston City Hospital, Boston, MA 02118
Nurse: Carol Saunders (617)534-5404
Coordinator: Ellen Godfrey (617)726-5596
Physician Contact: Donald Craven (617)534-4800
Status: Open ***Open Date:*** 10/01/89 ***Close Date:*** / /

Massachusetts General Hospital, Boston, MA 02114
Nurse: Teri Flynn (617)726-3819
Coordinator: Ellen Godfrey (617)726-5596
Physician Contact: Martin Hirsch (617)726-3812
Status: Open ***Open Date:*** 10/01/89 ***Close Date:*** / /

New England Deaconess Hospital, Boston, MA 02215
Nurse: Helen Fitch (617)732-9853
Coordinator: Ellen Godfrey (617)726-5596
Physician Contact: J. Davis Allan (617)732-9480
Status: Open ***Open Date:*** 10/01/89 ***Close Date:*** / /

Baystate Medical Center, Springfield, MA 01199
Nurse: Susan Oaks (413)784-5376
Coordinator: Charla Andrews (508)856-3456
Physician Contact: Michael Sands (413)784-5376
Status: Open ***Open Date:*** 10/20/89 ***Close Date:*** / /

University of Mass. Medical Center, Worcester, MA 01655
Nurse:
Coordinator: Charla Andrews (508)856-2456
Physician Contact: Sarah Cheeseman (508)856-3158
Status: Open ***Open Date:*** 10/20/89 ***Close Date:*** / /

Diagnosis: AIDS ARC

Other Information

*Dose, taken every 12 hours, depends on arm of trial and weight.
**All patients will be treated with aerosolized pentamidine for PCP prophylaxis. Patients who reach an endpoint on one arm of the study will be crossed over to the other.
Intractable diarrhea is also an exclusion criterion.

* * * * * * * * * *

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Protocol: ACTG 117 ***Sponsor:*** NIAID ***Phase:*** 2

Title: Comparison of ddI and AZT in therapy of patients with AIDS and ARC who have been treated with AZT for more than one year

Objective: Compare the safety and efficacy of ddI and AZT for patients with AIDS and ARC who have been treated long term with AZT

Drug Type: Antiviral ***Placebo:*** ***Inpatient:***
Drug: ddI ***Dose:*** High and low dose*
Route: PO
Duration: up to 18 months

Drug: AZT ***Dose:*** 100 mg q4h, 600 mg/day
Route: PO
Duration: up to 18 months

Drug: Pentamidine** ***Dose:*** 300 mg once a month
Route: aerosol
Duration: up to 18 months

Inclusion Criteria

1. AIDS or ARC with 1 symptom or more and CD4 less than 300
2. Prior AZT use, 12 months or more
3. Acceptable hematologic and chemistry parameters

Exclusion Criteria

Age < 12
1. KS requiring therapy
2. Significant neurologic disease including seizures
3. History of pancreatitis or heart disease
4. Prior therapy with ganciclovir
5. Ongoing acute opportunistic infection requiring therapy

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Location Information

Beth Israel Hospital, Boston, MA 02215
Nurse: Sheila Hussey (617)735-4103
Coordinator: Ellen Godfrey (617)726-5596
Physician Contact: Clyde Crumpacker (617)735-3528
Status: Open ***Open Date:*** 10/01/89 ***Close Date:*** / /

Boston City Hospital, Boston, MA 02118
Nurse: Carol Saunders (617)534-5404
Coordinator: Ellen Godfrey (617)716-5596
Physician Contact: Donald Craven (617)534-4800
Status: Open ***Open Date:*** 10/01/89 ***Close Date:*** / /

Massachusetts General Hospital, Boston, MA 02114
Nurse: Teri Flynn (617)726-3819
Coordinator: Ellen Godfrey (617)726-5596
Physician Contact: Martin Hirsch (617)726-3812
Status: Open ***Open Date:*** 10/01/89 ***Close Date:*** / /

New England Deaconess Hospital, Boston, MA 02215
Nurse: Helen Fitch (617)732-9853
Coordinator: Ellen Godfrey (617)726-5596
Physician Contact: J. Davis Allan (617)732-9840
Status: Open ***Open Date:*** 10/01/89 ***Close Date:*** / /

Baystate Medical Center, Springfield, MA 01199
Nurse: Susan Oaks (413)784-5376
Coordinator: Charla Andrews (508)856-2456
Physician Contact: Michael Sands (413)784-5376
Status: Open ***Open Date:*** 10/20/89 ***Close Date:*** / /

University of Mass. Medical Center, Worcester, MA 01655
Nurse:
Coordinator: Charla Andrews (508)856-2456
Physician Contact: Sarah Cheeseman (508)856-3158
Status: Open ***Open Date:*** 10/20/89 ***Close Date:*** / /

Diagnosis: AIDS ARC

Other Information

*Dose, taken every 12 hours, depends on arm of trial and weight.
**All patients will be treated with aerosolized pentamidine for PCP prophylaxis. Patients who reach an endpoint on one arm of the study will be crossed over to the other.
Elevated serum amylase is also an exclusion criterion.

* * * * * * * * * *

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Protocol: ACTG 118 ***Sponsor:*** NIAID ***Phase:*** 2

Title: Study of ddI administered orally twice daily to AZT-intolerant patients with AIDS and ARC

Objective: Compare the safety and efficacy of three doses of ddI for patients with hemotologic intolerance to AZT

Drug Type: Antiviral ***Placebo:*** ***Inpatient:*** N
Drug: ddI ***Dose:*** High, medium, low dose*
Route: PO
Duration: up to 18 months

Drug: Pentamidine** ***Dose:*** 300 mg/month
Route: aerosol
Duration: up to 18 months

Inclusion Criteria

1. AIDS or ARC with at least 1 symptom and CD4 less than 300
2. Prior AZT for at least 6 weeks
3. Acceptable hematologic and chemistry parameters

Exclusion Criteria

Age < 12
1. KS requiring therapy
2. Significant neurologic disease including seizures
3. History of pancreatitis or heart disease
4. Ongoing acute opportunistic infection requiring therapy
5. Elevated serum amylase

Location Information

Beth Israel Hospital, Boston, MA 02215
Nurse: Sheila Hussey (617)735-4103
Coordinator: Ellen Godfrey (617)726-5596
Physician Contact: Clyde Crumpacker (617)735-3661
Status: Open ***Open Date:*** 10/01/89 ***Close Date:*** / /

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Boston City Hospital, Boston, MA 02118
Nurse: Carol Saunders (617)534-5404
Coordinator: Ellen Godfrey (617)726-5596
Physician Contact: Donald Craven (617)534-4800
Status: Open ***Open Date:*** 10/01/89 ***Close Date:*** / /

Massachusetts General Hospital, Boston, MA 02114
Nurse: Teri Flynn (617)726-3819
Coordinator: Ellen Godfrey (617)726-5596
Physician Contact: Martin Hirsch (617)726-3812
Status: Open ***Open Date:*** 10/01/89 ***Close Date:*** / /

New England Deaconess Hospital, Boston, MA 02215
Nurse: Helen Fitch (617)732-9853
Coordinator: Ellen Godfrey (617)726-5596
Physician Contact: J. Davis Allan (617)732-9480
Status: Open ***Open Date:*** 10/01/89 ***Close Date:*** / /

Baystate Medical Center, Springfield, MA 01199
Nurse: Susan Oaks (413)784-5376
Coordinator: Charla Andrews (508)856-2456
Physician Contact: Michael Sands (413)784-5376
Status: Open ***Open Date:*** 10/20/89 ***Close Date:*** / /

University of Mass. Medical Center, Worcester, MA 01655
Nurse:
Coordinator: Charla Andrews (508)856-2456
Physician Contact: Sarah Cheeseman (508)856-3158
Status: Open ***Open Date:*** 10/20/89 ***Close Date:*** / /

Diagnosis: AIDS ARC

Other Information

*For weight >= 60 kg, high dose, 750 mg; medium, 500 mg; low, 200 mg. For weight < 60 kg, high dose, 500 mg; medium, 334 mg; low, 134 mg every 12 hours.
**All patients will be treated with aerosolized pentamidine for PCP prophylaxis.

* * * * * * * * * * *

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Protocol: ACTG 120 ***Sponsor:*** NIAID ***Phase:*** 2

Title: Itraconazole for primary histoplasmosis infection and suppression of disseminated histoplasmosis

Objective: Evaluation of itraconazole in treatment of primary histoplasmosis infection and prevention of relapse

Drug Type: Antifungal ***Placebo:*** N ***Inpatient:*** *
Drug: Itraconazole ***Dose:*** 300 mg bid (load)
Route: PO
Duration: 3 days

Drug: Itraconazole ***Dose:*** 200 mg bid (primary)
Route: PO
Duration: 12 weeks

Drug: Itraconazole ***Dose:*** 200 mg qd (maintenance)
Route: PO
Duration: 52 weeks

Inclusion Criteria

1. Diagnosis of AIDS
2. Histoplasmosis/disseminated histoplasmosis

Exclusion Criteria

Age < 12
1. Allergy to similar drugs
2. Pregnancy or breastfeeding

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Location Information

University of Mass. Medical Center, Worcester, MA 02111
Nurse:
Coordinator: Charla Andrews (508)856-2456
Physician Contact: Sarah Cheesman (508)856-3158
Status: Open ***Open Date:*** 06/01/90 ***Close Date:*** / /

Diagnosis: AIDS OI

Other Information

*Inpatient time depends on condition of patient.

* * * * * * * * * *

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Protocol: ACTG 128 ***Sponsor:*** NIAID ***Phase:*** 3

Title: Randomized double-blind trial of high versus low dose AZT in HIV-infected children

Objective: Evaluate tolerance and side-effects of 2 doses of AZT in mildly symptomatic HIV-infected children

Drug Type: Antiviral ***Placebo:*** N ***Inpatient:*** N
Drug: AZT ***Dose:*** 180 mg/m2 q6h
Route: PO
Duration: 104 weeks

Drug: AZT ***Dose:*** 90 mg/m2 q6h
Route: PO
Duration: 104 weeks

Inclusion Criteria

1. < 500 CD4 or
2. > 500 CD4 with symptoms

Exclusion Criteria

Age < 3 mo ***Age >*** 12
1. Diagnosis of AIDS
2. Eligibility for ACTG 051
3. Concurrent anti-HIV therapy
4. Concurrent intravenous immunoglobulin (IVIG)

Location Information

Boston City Hospital, Boston, MA 02118
Nurse: Anne Marie Regan (617)534-5813
Coordinator: Anne Marie Regan (617)534-5813
Physician Contact: Stephen Pelton (617)534-5506
Status: Open ***Open Date:*** / / ***Close Date:*** / /

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Children's Hospital, Boston, MA 02215
Nurse: Andrea Rubin (617)735-7879
Coordinator: Kerrie Liebendorfer (617)735-8198
Physician Contact: Lynn Luginbuhl (617)735-6369
Status: Open ***Open Date:*** 02/01/90 ***Close Date:*** / /

Baystate Medical Center, Springfield, MA 01199
Nurse:
Coordinator: Susan Oaks (413)784-5376
Physician Contact: Barbara Stechenberg (413)784-0000
Status: Open ***Open Date:*** 01/01/90 ***Close Date:*** / /

University of Mass. Medical Center, Worcester, MA 01655
Nurse: Amy Sharples (508)856-3874
Coordinator: Charla Andrews (508)856-2456
Physician Contact: John Sullivan (508)856-6282
Status: Open ***Open Date:*** 10/13/89 ***Close Date:*** / /

Diagnosis: Pediatric HIV infx

* * * * * * * * * *

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Protocol: ACTG 134 ***Sponsor:*** NIAID ***Phase:*** 1

Title: Safety and pharmacokinetics (PK) of oral AZT plus intravenous immunoadhesion (rCD4-IgG)

Objective: Assess the safety and pharmacokinetics of combination therapy of IV rCD4-IgG and AZT

Drug Type: Antiviral ***Placebo:*** N ***Inpatient:*** N
Drug: AZT ***Dose:*** 300 or 600 mg/day
Route: PO
Duration: 12 weeks

Drug: rCD4-IgG ***Dose:*** 300 or 1000 mcg/kg biwk
Route: IV
Duration: 12 weeks

Inclusion Criteria

1. Diagnosis of AIDS or ARC or asymptomatic HIV+ with positive p24
2. < 500 CD4
3. < 120 days prior use of AZT
4. Acceptable hematologic/chemistry parameters

Exclusion Criteria

Age < 18
1. Pregnancy or breastfeeding
2. Antiviral drugs within preceding 3 weeks

Location Information

University of Mass. Medical Center, Worcester, MA 01655
Nurse: Carol Bora (508)856-2456
Coordinator: Charla Andrews (508)856-2456
Physician Contact: Sarah Cheeseman (508)856-3158
Status: Open ***Open Date:*** 05/01/90 ***Close Date:*** / /

Diagnosis: AIDS ARC Asymptomatic

Other Information

If improvement is seen after 12 weeks, patient may, at investigator's discretion, be allowed to have maintenance therapy.

* * * * * * * * * * *

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Protocol: AI455-003 ***Sponsor:*** Bristol-Myers ***Phase:*** 1

Title: Dose ranging study of d4T administered twice daily to AZT-intolerant patients with AIDS or ARC

Objective: Assess safety and efficacy of d4T in AZT-intolerant AIDS and ARC patients

Drug Type: Antiviral ***Placebo:*** N ***Inpatient:*** N
Drug: d4T ***Dose:*** 0.5/1.0/2.0/3.0 mg/kg/day
Route: PO
Duration: 52 weeks

Inclusion Criteria

1. CDC group IVA, IVC2 (ARC or AIDS)
2. Intolerance to <= 600 mg AZT per day *
3. < 500 CD4
4. Hgb >= 8.5
5. PMN >= 750

Exclusion Criteria

Age < 18
1. Active AIDS-defining OI
2. Systemic maintenance therapy for OI
3. Seizures requiring anticonvulsant medication
4. Intractable diarrhea

Location Information

Roger Williams General Hospital, Providence, RI 02908
Nurse: Grace Accetta (401)456-2437
Coordinator: Stephanie Chafee (401)456-2437
Physician Contact: Gail Skowron (401)456-2437
Status: Open ***Open Date:*** 05/01/90 ***Close Date:*** / /

Diagnosis: AIDS ARC

Other Information

* AZT intolerance is defined by fall in hgb of 2 g/dl to <= 9.0 g/dl or fall in neutrophils of at least 200 mm3 to <= 750. Aerosolized Pentamidine or Bactrim permitted for PCP prophylaxis.

* * * * * * * * * *

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Protocol: BUCRC 002 ***Sponsor:*** Adria ***Phase:*** 1

Title: Study of Thymic Humoral Factor-Gamma 2 on HIV infection in patients treated with AZT

Objective: Assess safety and immunomodulatory effects of THF-Gamma 2 in HIV-infected patients on AZT

Drug Type: Antiviral/Immunomod ***Placebo:*** N ***Inpatient:*** N
Drug: THF-Gamma 2 ***Dose:*** 5/10/25/50 mg/kg/day
Route: IM *
Duration: 12 weeks **

Drug: AZT (not supplied) ***Dose:*** 500-1200 mg/day
Route: PO
Duration: 26 weeks

Inclusion Criteria

1. Skin test reactivity to < 3 of 7 antigens
2. HIV+
3. AZT therapy at least 6 weeks before entry
4. Acceptable hematologic and chemical parameters

Exclusion Criteria

Age < 18
1. Active OI or malignancy requiring systemic Rx
2. Transfusion dependent
3. PCP prophylaxis other than aerosol pentamidine

Location Information

Roger Williams General Hospital, Providence, RI 02908
Nurse: Grace Accetta (401)456-2437
Coordinator: Stephanie Chafee (401)456-2437
Physician Contact: Gail Skowron (401)456-2437
Status: Open ***Open Date:*** 11/15/89 ***Close Date:*** / /

Diagnosis: HIV+

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Other Information

AZT is not supplied or paid for by the study.
* Self-injection option is available.
**Extension protocol is available.

* * * * * * * * * * *

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Protocol: C89-258 ***Sponsor:*** Schering-Plough ***Phase:*** 2

Title: SCH 39304 as therapy for acute cryptococcal meningitis in HIV-infected patients followed by maintenance therapy

Objective: Assess safety and efficacy of SCH 39304 as primary and maintenance therapy for cryptococcal meningitis

Drug Type: Antifungal ***Placebo:*** N ***Inpatient:*** N
Drug: SCH 39304 ***Dose:*** 200 mg qd
Route: PO
Duration: 12 weeks

Drug: SCH 39304 ***Dose:*** 600 mg/wk or 100 mg/qd
Route: PO
Duration: 52 weeks

Inclusion Criteria

1. Male or female at least 13 years
2. Acceptable cerebal spinal fluid culture
3. Documented HIV+

Exclusion Criteria

Age < 12
1. Karnofsky > 20
2. Concomitant cytotoxic medication
3. Active concurrent CNS disease or acute OI requiring medication
4. Oral hypoglycemics or oral contraceptives
5. Unacceptable hematologic or chemistry parameters

Location Information

Boston University Medical Center, Boston, MA 02118
Nurse: Nancy Salitsky (800)802-1092
Coordinator: Carol Saunders (617)638-5494
Physician Contact: Alan Sugar (617)638-7909
Status: Open ***Open Date:*** 12/01/89 ***Close Date:*** / /

Diagnosis: OI

Other Information

SCH 39304 is a triazole.

* * * * * * * * * * *

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Protocol: FDA 11A ***Sponsor:*** Rhone-Poulenc ***Phase:*** Openlbl

Title: Open-label compassionate use study of spiramycin for treatment of diarrhea caused by chronic cryptosporidiosis in immunocompromised

Objective: Make spiramycin available for treatment of cryptosporidiosis in immunocompromised patients; collect data on safety and efficacy

Drug Type: Antiparasitic ***Placebo:*** N ***Inpatient:*** N
Drug: Spiramycin ***Dose:***
Route: PO
Duration: Indefinite

Inclusion Criteria

1. Diagnosis of chronic diarrhea from cryptosporidiosis
2. Immune suppression from HIV, chemotherapy, or organ transplant

Exclusion Criteria

Age < 18
1. Pregnancy or breast-feeding
2. Concurrent use of other investigational drugs
3. Sensitivity to macrolide antibiotics

Location Information

Rhone-Poulenc Pharmaceuticals, Princeton, NJ 08540
Nurse: Cindy Hunt (609)520-0880
Coordinator:
Physician Contact:
Status: ***Open Date:*** / / ***Close Date:*** / /

Diagnosis: Immunocompromised

Other Information

This protocol is for immunocomprised patients and not limited to PWAs.

* * * * * * * * * *

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Protocol: FDA 12C ***Sponsor:*** Pfizer ***Phase:*** Openlbl

Title: Non-comparative study of fluconazole in patients with serious mycoses who cannot be treated with conventional antifungal therapy

Objective: Provide fluconazole to people with conditions for which it has not been approved

Drug Type: Antifungal ***Placebo:*** N ***Inpatient:*** N
Drug: Fluconazole ***Dose:***
Route: IV or PO
Duration: Variable

Inclusion Criteria

1. Documented serious fungal disease*
2. failure of or intolerance to conventional therapy(amphotericin B)

Exclusion Criteria

Age < 18
1. Previous adverse reaction to fluconazole

Location Information

Pfizer Central Research, Groton, CT 06340
Nurse: (203)441-4812
Coordinator:
Physician Contact:
Status: Open ***Open Date:*** / / ***Close Date:*** / /

Diagnosis: OI

Other Information

* This protocol is for conditions for which fluconazole has not already been approved, e.g. histoplasmosis, blastomycosis, coccidioidomycosis.
Physicians should contact Pfizer at number given above.

* * * * * * * * * *

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Protocol: FDA 31B ***Sponsor:*** Hoffman-LaRoache ***Phase:*** Openlbl

Title: Safety study of dideoxycytidine(ddC) in AIDS and ARC patients for whom AZT and ddI have been ineffective

Objective: Provide ddC AIDS and ARC patients who have failed or been intolerant to AZT and ddI; demonstrate safety of ddC monotherapy

Drug Type: Antiviral ***Placebo:*** N ***Inpatient:*** N
Drug: ddC ***Dose:***
Route: PO
Duration: Indefinite

Inclusion Criteria

1. AZT failure or intolerance
2. ddI intolerance
3. Acceptable hematologic and chemistry parameters

Exclusion Criteria

Age < 18
1. Pregnancy or breast-feeding
2. History of peripheral neuropathy
3. Neoplasms other than KS or basal cell carcinoma
4. Therapy with other experimental drugs

Location Information

Hoffman-LaRoche, Nutley, NJ 07110
Nurse: (800)332-2144
Coordinator:
Physician Contact:
Status: Open ***Open Date:*** / / ***Close Date:*** / /

Diagnosis: AIDS ARC

* * * * * * * * * * *

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Protocol: FDA 39A ***Sponsor:*** Bristol-Myers ***Phase:*** Openlbl

Title: An open label study of ddI in patients with AIDS for whom AZT is not effective

Objective: Make ddI available to patients with AIDS who are clinically deteriorating and unable to enter Phase 2 ddI protocol

Drug Type: Antiviral ***Placebo:*** N ***Inpatient:*** N
Drug: ddI ***Dose:*** 167, 250, 375 mg/kg bid
Route: PO
Duration:

Inclusion Criteria

1. AIDS with Karnofsky 40% or less
2. 500 mg daily at least 6 months
3. Not suitable for Phase 2 ddI study
4. Able to provide informed consent, and for monthly follow-up
5. Significant weight loss, neurological deterioration

Exclusion Criteria

Age < 12
1. Anti-retroviral therapy in previous 15 days
2. Taking AZT or phenytoin concomitantly
3. Pregnancy or breast-feeding
4. Acute pancreatitis
5. Poorly controlled seizure disorder

Location Information

Bristol-Myers Squibb, Evansville, IN
Nurse: (800)662-7999
Coordinator:
Physician Contact:
Status: ***Open Date:*** / / ***Close Date:*** / /

Diagnosis: AIDS AIDS neurological OI

Other Information

This program is available for patients with AIDS who cannot participate in Phase 2 ddI trial because of exclusion criteria or by reason of geographic location.
Physicians may obtain more information by calling 1-800-662-7999 between 8 a.m. and 8 p.m. EST.

* * * * * * * * * * *

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Protocol: FDA 39C ***Sponsor:*** Bristol-Myers ***Phase:*** Openlbl

Title: Open label study of ddI in children with AIDS for whom AZT in not effective

Objective: Make ddI available to children with AIDS who are clinically deteriorating and unable to enter Phase 2 ddI protocol

Drug Type: Antiviral ***Placebo:*** N ***Inpatient:*** N
Drug: ddI ***Dose:***
Route: PO
Duration: Indefinite

Inclusion Criteria

1. AIDS with significant deterioration despite or intolerance to AZT
2. < 400 CD4
3. Parent's or guardian's informed consent
4. Acceptable hematologic and laboratory parameters

Exclusion Criteria

Age < 3 ***Age*** > 13
1. Acute pancreatitis
2. Seizures or history of seizure disorder
3. Pre-existing cardiomyopathy
4. Grade I or greater peripheral neuropathy
5. Taking AZT or chemotherapy with cytotoxic agents

Location Information

Bristol-Myers Squibb, Wallingford, CT 06492
Nurse:
Coordinator:
Physician Contact: Laurie Smaldone (203)284-5000
Status: Open ***Open Date:*** / / ***Close Date:*** / /

Diagnosis: AIDS AIDS neurological OI

Other Information

This study is similar to the adult study FDA 39A, but intended for children.

* * * * * * * * * *

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Protocol: FDA 40A ***Sponsor:*** Bristol-Myers ***Phase:*** IND

Title: A treatment IND for use of dideoxyinosine (ddI) in patients with AIDS, intolerant to AZT or ineligible for Phase 2 ddI study

Objective: Make ddI available to patients with AIDS or ARC

Drug Type: Antiviral ***Placebo:*** N ***Inpatient:*** N
Drug: ddI ***Dose:*** 167, 250, 375 mg/kg bid
Route: PO
Duration:

Inclusion Criteria

1. HIV+ with CD4 < 200 or CDC-defined AIDS
2. Intolerant to AZT
3. Not suitable for Phase 2 ddI study
4. Available for monthly follow-up

Exclusion Criteria

Age < 12
1. Previous antiviral (not AZT) therapy 15 days prior
2. Taking AZT concomitantly
3. Malignancy requiring systemic chemotherapy
4. Pregnancy or breast-feeding
5. Acute pancreatitis

Location Information

Bristol-Myers Squibb, Evansville, IN
Nurse: (800)662-7999
Coordinator:
Physician Contact:
Status: Open ***Open Date:*** / / ***Close Date:*** / /

Diagnosis: AIDS ARC

Other Information

This treatment IND is available to patients who cannot participate in ongoing formal studies by Bristol-Myers due to criteria exclusion or geographic location.
Physicians may obtain more information by calling 1-800-662-7999 between 8 a.m. and 8 p.m. EST.

* * * * * * * * * *

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Protocol: FDA 4G ***Sponsor:*** Biotech ***Phase:*** IND

Title: Erythropoietin treatment program for anemia in AIDS patients

Objective: Provide EPO for treatment of anemia in people with AIDS

Drug Type: Synthetic hormone ***Placebo:*** N ***Inpatient:*** N
Drug: Erythropoietin (Eprex) ***Dose:*** 24,000 units/week
Route: Subcutaneous
Duration: Indefinite

Inclusion Criteria

1. WBC > 1500
2. Platelets > 75000
3. HCT < 30%
4. SGOT under 2x normal
5. Bilirubin under 1.25x normal

Exclusion Criteria

Age < 12
1. Uncontrolled hypertension (diastolic > 100 mmHg)
2. Anemia attributable to other causes
3. Active OI except esophageal candidiasis
4. Cytotoxic chemotherapy one month prior to initiating Eprex
5. History of seizures

Location Information

, ,
Nurse: Eprex hotline (800)243-7739
Coordinator:
Physician Contact:
Status: ***Open Date:*** / / ***Close Date:*** / /

Diagnosis: AIDS

Other Information

This protocol is a treatment IND. Enrollment information is available from the Eprex hotline, 1-800-243-7739.

* * * * * * * * * *

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Protocol: N3300 ***Sponsor:*** Hoffman-LaRoche ***Phase:*** 2/3

Title: Dideoxycytidine (ddC) versus Zidovudine (AZT) in patients with AIDS or ARC

Objective: To determine the effectiveness of ddC in patients with ARC and AIDS

Drug Type: Antiviral ***Placebo:*** N ***Inpatient:*** N
Drug: ddC ***Dose:*** .75 mg q8h
Route: PO
Duration: 104 weeks

Drug: AZT ***Dose:*** 100 mg q4h
Route: PO
Duration: 104 weeks

Drug: Pentamidine ***Dose:*** 300 mg/q month
Route: aerosol
Duration: 104 weeks

Inclusion Criteria

1. ARC (diarrhea, weight loss, fevers, thrush)
2. PCP within 120 days
3. < 200 CD4 cells
4. Platelets >100,000

Exclusion Criteria

Age < 18
1. Intolerance to AZT
2. More than 3 months of AZT therapy
3. Peripheral neuropathy
4. Pregnancy or breast-feeding

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Location Information

New England Medical Center, Boston, MA 02111
Nurse: Barbara Donnelly (617)956-5114*
Coordinator:
Physician Contact: Paul Skolnik (617)956-7008
Status: Open ***Open Date:*** 08/31/89 ***Close Date:*** / /

Diagnosis: AIDS ARC OI PCP

Other Information

Aerosolized pentamidine will be offered to all patients
* beeper no. 2446

* * * * * * * * * * *

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Protocol: NS 401 ***Sponsor:*** Warner-Lambert ***Phase:*** IND

Title: Trimetrexate with leucovorin rescue of AIDS patients who are not eligible for randomized trials for treatment of refractory PCP

Objective: Determine safety and efficacy of TMTX/LCV therapy in patients who have failed or been intolerant to conventional PCP therapies

Drug Type: Antifungal ***Placebo:*** N ***Inpatient:*** Y
Drug: Trimetrexate ***Dose:*** 45 mg/m2 qd
Route: IV
Duration: 21 days

Drug: Leucovorin ***Dose:*** 30 mg/m2 q6h
Route: PO, IV
Duration: 24 days

Inclusion Criteria

1. Failure to respond to 7 days each of treatment with T/S and AP or
2. Intolerance to one of above and failure to respond to other
3. Acceptable hematologic and chemistry parameters

Exclusion Criteria

Age < 12
1. Pregnacny or breast-feeding
2. History of Type I hypersensitivity, allergy to study medication
3. Treatment with myelosuppressive or nephrotoxic agents

Location Information

Warner-Lambert Parke-Davis, Morris Plains, NJ 07950
Nurse: (800)537-9978
Coordinator:
Physician Contact:
Status: ***Open Date:*** / / ***Close Date:*** / /

Diagnosis: PCP

* * * * * * * * * * *

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Protocol: NS 402 ***Sponsor:*** NIAID ***Phase:*** Openlbl

Title: Open protocol for AZT as prophylactic treatment after accidental massive exposure to HIV

Objective: Prevent infection in persons who have had massive accidental exposure to HIV

Drug Type: Antiviral ***Placebo:*** N ***Inpatient:*** N
Drug: AZT ***Dose:*** 200 mg q4h
Route: PO
Duration: 42 days

Inclusion Criteria

1. HIV negative
2. Significant exposure to HIV within previous 5 days*
3. Acceptable hematologic and chemistry parameters

Exclusion Criteria

Age < 13
1. Pregnancy or breast-feeding
2. Prior diagnosis of HIV infection
3. p24 antigen positive
4. Liver dysfunction
5. Compromised bone marrow function

Location Information

Burroughs-Wellcome, Research Triangle, NC 27709
Nurse: (800)537-9978
Coordinator:
Physician Contact:
Status: ***Open Date:*** / / ***Close Date:*** / /

Diagnosis: HIV negative

Other Information

* May include exposure as a result of accidental innoculation through an open wound or puncture; from organ transplants from infected donors; from blood transfusions and exposure to blood products from infected donors; from artificial insemination with semen from an infected donor.

* * * * * * * * * * *

MASSACHUSETTS CLINICAL TRIALS DIRECTORY FOR AIDS AND HIV-RELATED DRUGS

Protocol: TX 301 ***Sponsor:*** Warner-Lambert ***Phase:*** IND

Title: Treatment protocol for Trimetrexate with Leucovorin rescue for patients with PCP and serious intolerance to approved therapies

Objective: Determine safety and efficacy of TMTX/LCV therapy in patients who have demonstrated adverse effects from conventional therapies

Drug Type: Antifungal ***Placebo:*** N ***Inpatient:*** Y
Drug: Trimetrexate ***Dose:*** 45 mg/m2 qd
Route: IV
Duration: 21 days

Drug: Leucovorin ***Dose:*** 30 mg/m2 q6h
Route: PO, IV
Duration: 24 days

Inclusion Criteria

1. Intolerance to trmethoprim/sulfamethoxazole
2. Intolerance to pentamidine
3. Acceptable hematologic and chemistry parameters

Exclusion Criteria

Age < 12
1. Pregnancy or breast-feeding
2. Treatment with myelosuppressive or nephrotoxic agents
3. Treatment with other investigational drugs

Location Information

Warner-Lambert Parke-Davis, Morris Plains, NJ 07950
Nurse: (800)537-9978
Coordinator:
Physician Contact:
Status: ***Open Date:*** / / ***Close Date:*** / /

Diagnosis: PCP

* * * * * * * * * * *

GLOSSARY

Acylovir: An antiviral drug shown to be effective against herpes virus infections.

AIDS Clinical Trial Group (ACTG): Experimental drug testing system administered by the National Institute of Allergy and Infectious Diseases to test AIDS-related drugs.

AIDS (Acquired Immune Deficiency Syndrome): A complex disease characterized by severe damage to the body's natural immune system. A person with AIDS becomes susceptible to diseases and cancers that are not ordinarily a threat to people with normal immune systems. Diseases and cancers that threaten people who are immune-suppressed are called opportunistic infections (see below).

AIDS-Related Complex (ARC): A condition in which some of the symptoms of AIDS have appeared, for example, candidiasis and/or lymphadenopathy (see below), but none of the opportunistic infections used to define the syndrome has appeared.

ANC: Absolute netrophil count.

Antibiotics: Drugs that help the body to kill invading microorganisms such as bacteria, fungi or protozoa.

Antibody: A protein produced by the B-lymphocytes (see below) that attacks foreign substances or microorganisms that invade the body and helps destroy them. When one has developed antibodies to a particular substance or microorganism, one is usually immune to that specific substance or microorganism in the future.

Antifungal: A drug which has activity against fungal infections.

Antigen: A substance or microorganism recognized by the immune system (see below) as foreign. A normal immune system attempts to destroy invading antigens.

Antiviral: A substance that is directed at a virus to inhibit or stop its destructive activity toward healthy cells.

ARC: AIDS-Related Complex (see above).

Azidothymidine (AZT, Retrovir, Zidovudine): A drug which inhibits replication of HIV and has been shown to prolong the life of patients with HIV infection. Currently it is the only antiviral drug licensed in the U.S.A. for treatment of HIV infection.

AZT: see Azidothymidine.

B-lymphocytes (B-cells): White blood cells that produce antibodies.

Bacterium: A small microorganism made up of a single cell. There are hundreds of different bacteria, and many may cause disease.

Bioavailability: The degree and weight at which a substance (drug) is absorbed into a living system.

Biopsy: A procedure in which a small sample of some tissue or organ is removed for laboratory examination. Many biopsies are performed with long needles with special tips that are pushed into the body to extract tissue.

Bone marrow: The spongy substance found in the hollow parts of long bones in the arms and legs. It produces blood cells.

Cancer: The uncontrolled growth of the cells of the tissues of any organ in the body. Cancers can destroy the tissues surrounding them and can spread to different part of the body.

Candidiasis: A fungal infection that usually occurs in the mouth or throat. It is called thrush or yeast infection and is caused by a candida fungus. Candidiasis is one of the conditions associated with ARC (see above)

CD4: The T-cell (see below) identifying molecule expressed on certain types of lymphocytes. The number of CD4 cells per cubic millimeter is a marker of immune function. Recombinant and soluble CD4s are are artificially produced substances that mimic CD4 receptor sites on T-cells and have been shown to block HIV infection in test tube studies.

Cerebrospinal Fluid: The fluid that surrounds the brain and spinal cord.

Chemotherapy: Treatment of cancer with drugs, or chemicals.

CMV: See Cytomegalovirus.

CNS: Central nervous system.

Compassionate Use: See Treatment IND.

Controlled Studies: Studies in which patients receiving an experimental treatment (new drugs, different doses, new routes of administration) are compared to a similar group of patients who are receiving a control treatment. The control treatment may be a standard treatment if one exists, or a placebo treatment if there is no standard therapy for the condition.

Cryptococcus: A usually harmless fungus that causes meningitis in persons with AIDS. It is very difficult to cure because drugs currently available to treat it are highly toxic.

Cryptosporidiosis: A protozoan infection that is usually self-limiting in persons with normal immune systems. In persons with AIDS, cryptosporidiosis can cause severe diarrhea, dehydration, and malnutrition.

CSF: Cerebrospinal fluid.

Cytomegalovirus (CMV): A virus in the herpes family that is found in a large population. It does not cause disease if the immune system is normal, but in persons with AIDS it can cause disease in the lungs, eyes, brain, colon, and other organs.

ddC: see Dideoxycytidine.

Dideoxycytidine (ddC): A drug similar to azidothymidine which is currently being studied in patients infected with HIV.

Dideoxyinosine (ddI): A drug similar to azidothymidine and dideoxycytidine which is currently being studied in patients infected with HIV.

Fluconazole: An experimental antifungal agent.

Fungus: Any of the members of a group of organisms that includes yeast, molds, mildew, and mushrooms.

GM-CSF: Granulocyte-monocyte colony stimulating factor; a substance being tested for its ability to restore certain cells of the bone marrow (see above).

Hemophilia: A hereditary disorder that prevents proper clotting of blood. It occurs almost exclusively in males.

Hepatitis: An inflammation of the liver that can cause the skin and eyes to turn yellow, and can cause malaise, vomiting, and pain. It can have any of several causes, but is usually caused by viral infections.

Herpes simplex: A herpes virus that causes cold sores around the mouth or genital area. These usually heal by themselves after a while. In persons with AIDS, however, these virus sores require the intervention of a drug to heal.

Herpes virus: A family of large viruses that contain a large amount of DNA. They include herpes simplex, herpes zoster, cytomegalovirus, and Epstein-Barr virus.

Herpes zoster: The virus that causes chicken pox and shingles. In AIDS patients, it can also infect sections of the body along nerve roots, presented as patches of red bumps on the skin.

HIV (Human Immunodeficiency Virus): The retrovirus formerly identified as HTLV-III/LAV, accepted by the majority of the medical community as the cause of AIDS.

IM: Intramuscular(ly) or into the muscle.

Immune: Resistant to disease; able to form effective antibodies against disease.

Immune system: The complex system made up of interacting cells and proteins by which the body fights infectious diseases.

Immunomodulator: Any agent or substance that triggers or enhances the body's defenses; also called immunostimulants.

IND: See Investigational New Drug.

Interferons: Natural proteins made by the white blood cells in response to the invasion by some foreign organism into the body.

Investigational New Drug: Designation for experimental drug after the FDA has approved an application for testing the drug on human subjects.

IV: Intravenous(ly) or through the vein.

IVIG: Intravenous immunoglobulin; a substance being tested for its ability to reduce bacterial infections in children with HIV infection.

Kaposi's sarcoma (KS): A cancer of the small blood vessels ordinarily first appearing on the skin of the legs or arms. In AIDS patients, KS may be a very aggressive disease.

Lumbar puncture: A procedure by which a sample of CSF is taken by a needle from the space surrounding the spinal cord. The CSF obtained this way is important in the diagnosis of infections of the brain.

Lymph nodes: Tissue located in the groin, neck, underarms, and various locations on the body, which fight infections by filtering out microorganisms and producing hormones, and which contain large numbers of lymphocytes.

Lymphadenopathy: A condition characterized by persistent swelling of the lymph nodes, sometimes thought to be an early sign of infection with the virus associated with AIDS.

Lymphocytes: Specialized, small, white blood cells that are very important in immunity. Lymphocytes are manufactured in the bone marrow and are altered in other organs to become T-lymphocytes or B-lymphocytes.

Lymphoma: A cancer of the lymphatic system.

Meningitis: Infection and inflammation of the membranes around the brain and the spinal cord.

Microbes: Organisms that can be seen only under a microscope.

Mycoses: A general term for fungal infections.

Neutrophil: A blood cell especially important in controlling bacterial infections.

OI: Opportunistic infection.

Opportunistic infection: Any of a number of infections that are caused by microorganisms ordinarily found in the environment, but which do not cause disease except in persons with damaged immune systems.

p24 viral antigen: A structural component of HIV which may be measured directly in blood and tissues of infected individuals.

Parasite: An organism that depends on a host for food and hence for its survival.

PCP: Pneumocystis Carinii Pneumonia.

Pentamidine: A drug used against PCP.

Pharmacokinetics: Studies done to determine how well a drug is taken up by the body, and how the body changes or metabolizes the drug to dispose of it.

Placebo: An inactive substance, with no directed beneficial efects, which may be used in some clinical studies as a guidepost to measure an experimental drug's effectiveness.

Plasma: The liquid part of the blood that contains minerals and proteins.

Platelet: A component of the blood that plays an important part in helping blood to clot. Without platelets any wound could result in death by bleeding.

***Pneumocystis Carinii* Pneumonia (PCP):** A pneumonia caused by a fungal infection, pneumocystis carinii. It does not ordinarily cause disease in people with normal immune systems, but it is a leading cause of death in persons with AIDS.

PO: Per os, Latin for "given by mouth".

Prophylaxis: Prevention of disease; measures preventing the development or spread of disease.

q: Abbreviation for Latin "quaque", meaning "every"; refers to the frequency of a medication or treatment, i.e. qd = every day, q4 = every four hours.

Refractory: Not responding to therapy.

Retrovir: Product name for azidothymidine or zidovudine.

Retrovirus: A virus that contains RNA, and not DNA as its genetic material. Retroviruses produce an analogue (a kind of mirror image) of their RNA by using an enzyme known as "reverse transcriptase." What results is DNA that incorporates itself into the genetic material of the cell that the virus has invaded. Scientists hope that by interfering with this "reverse transcriptase" they can prevent the retrovirus from replicating itself in the host cell.

Reverse Transciptase: An enzyme produced by retroviruses that allows them to produce a DNA copy of their RNA. This is the first step in their natural cycle of reproduction.

RNA (ribanucleic acid): Basic genetic material. A nucleic acid associated with the control of chemical activities inside a cell.

Salvage: A second phase of antimetabolic durg treatment designed to save normal cells from the effects of the drug.

Steroids: A group of hormones that reduce inflammation.

T-helper lymphocytes (T-4 cells): A subset of T-lymphocytes that form a key component in the body's defense against invading organisms. They signal the immune system to produce antibodies to invading organisms.

T-lymphocyte: A type of white blood cell that matures in the thymus gland and helps protect the body against a number of microorganisms, such as viruses, fungi, and parasites. T-lymphocytes also release substances that cause B-lymphocytes to proliferate.

T-suppressor lymphocytes (T-8 cells): A subset of T-lymphocytes that signal the immune system to stop the production antibodies.

Thrush: An infection in the mouth, tongue, and throat caused by a candida fungus. (see candidiasis).

Thymus gland: An organ in the neck that helps in the development of T-lymphocytes and produces hormones that help in maintaining the immune system. The 'T' in T-cell and T-lymphocyte refers to thymus.

Toxoplasmosis: A disease caused by the protozoan parasite toxoplasma gondii. It is almost never a threat to persons with normal immune systems, but is a serious problem for persons with AIDS, often causing infections of the brain.

Treatment IND: A procedure, subject to approval by the FDA, by which certain INDs are made available to patients with serious illnesses who have fialed standard therapies or for whose conditions there is no approved drug. The term is often used synonymously with "Compassionate Use".

Tumor: Any abnormal growth, whether it is cancerous or not.

Virus: A submicroscopic organism that is not a complete cell. It depends totally on living cells for survival and causes numerous diseases such as colds, flues, chicken pox, and measles.

White blood cells: Blood cells whose primary function is to fight infections.

Zidovudine: Generic name for azidothymidine.

Order Form for More Clinical Trials Information

Check off the items you would like to receive. Where foreign language versions of the publication are available, please circle the language of your choice:

1. **Massachusetts Clinical Trials Directory for AIDS and HIV-Related Drugs** _____

2. **Clinical Trials: Information Related to AIDS and HIV Infection** _____
   An informative pamphlet for health care providers and the public.

   Languages: English Spanish

3. **An Introduction to Clinical Trials** _____
   A public education brochure.

   Languages: English Spanish Portuguese Haitian Creole

4. **AIDS Clinical Trials and Research: Considerations for Patients and Primary Care Providers** _____
   A monograph for health care providers.

Name _____

Organization/Agency _____

Address _____

_____

_____

Telephone _____ Date

Return this form to: Clinical Trials Information Series
AIDS Office
Department of Public Health
150 Tremont Street
Boston, MA 02111

E R R A T U M:

The following protocol was inadvertently omitted from the July 1990 Directory. This protocol is still open for enrollment.

MASSACHUSETTS CLINICAL TRIALS DIRECTORY
FOR AIDS AND HIV-RELATED DRUGS

Protocol: 88-1029-69 ***Sponsor:***

Title: HUMAN RECOMBINANT GM-CSF IN COMBINATION WITH INTERFERON-2 ALPHA & AZT IN PTS WITH KAPOSI'S SARCOMA

Objective: ASSESS TOXICITY AND EFFICACY OF THIS THREE DRUG COMBINATION

Drug Type: ANTIVIRAL/IMMUNOMOD ***Placebo:*** N ***Inpatient:*** N
Drug: AZT ***Dose:*** 100 MG Q4 X 6
Route: PO
Duration: OPEN

Drug: INTERFERON ALPHA ***Dose:*** 9 m U
Route: IM
Duration: OPEN

Drug: GM-CSF ***Dose:*** VARIABLE
Route: SUBCUTANEOUS
Duration: OPEN

Inclusion Criteria

1. HISTOLOGICALLY PROVEN KAPOSI'S SARCOMA W/MEASURABLE DISEASE
2. PRESERVED LIVER AND KIDNEY FUNCTION
3. ACCEPTABLE HEMATOLOGIC AND CHEMISTRY PARAMETERS
4. AMBULATORY
5. AMBULATORY

Exclusion Criteria

1. ACTIVE OI
2. OTHER MALIGNANCY
3. CNS, CARDIAC, OR SIGNIFICANT PULMONARY DISEASE
4. PREVIOUS SEIZURE DISORDER
5. PREGNANT OR LACTATING WOMEN; OTHER INVESTIGATIONAL DRUGS

Location Information

NEW ENGLAND DEACONESS HOSPITAL, BOSTON, MA 02215
Nurse: JOCELYN BRESNAHAN (617)732-8540
Coordinator:
Physician Contact: DAVID SCADDEN (617)732-8540
Status: OPEN ***Open Date:*** 01/01/89 ***Close Date:***

Diagnosis: KS

* * * * * * * * * *